

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SMITHKLINE BEECHAM CORPORATION	)	
d/b/a GLAXOSMITHKLINE,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 09-608 (JJF)
	)	
GLENMARK GENERICS INC., USA,	)	
	)	
Defendant.	)	
	)	

**PLAINTIFF'S ANSWER TO  
GLENMARK GENERICS INC., USA'S COUNTERCLAIMS**

Plaintiff SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), for its Answer to the Counterclaims of Defendant Glenmark Generics Inc., USA ("Glenmark"), hereby states as follows:

**COUNTERCLAIM PARAGRAPH NO. 46:**

Glenmark Generics Inc., USA is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 46:**

Upon information and belief, GSK admits that Glenmark is a Delaware corporation with a place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. GSK is without knowledge or information sufficient to form a belief as to the truth of the remaining averments of Counterclaim Paragraph 46.

**COUNTERCLAIM PARAGRAPH NO. 47:**

On information and belief, Smithkline (*sic*) Beecham Corporation d/b/a GlaxoSmithKline is a Pennsylvania corporation with its principal place of business located at One Franklin Plaza, Philadelphia, Pennsylvania 19102.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 47:**

GSK admits that it is a Pennsylvania corporation having a place of business located at One Franklin Plaza, Philadelphia, PA 19102. To the extent that Counterclaim Paragraph 47 contains any other or different averments, GSK denies them.

**COUNTERCLAIM PARAGRAPH NO. 48:**

Jurisdiction of this Court is based upon 28 U.S.C. §§ 1331, 1338(a), and 1367(a); the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*; and 35 U.S.C. § 271(e)(2).

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 48:**

GSK admits that Glenmark purports to bring declaratory judgment counterclaims that arise under 28 U.S.C. §§ 1331, 1338(a), and 1367(a); the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*; and 35 U.S.C. § 271(e)(2). GSK, however, denies that there is any factual or legal basis for any of these counterclaims. GSK admits that Glenmark, by infringing United States Patent Nos. 6,166,046 (“the ’046 Patent”), 6,291,488 (“the ’488 Patent”), and 5,998,449 (“the ’449 Patent”), has created an actual and justiciable controversy between GSK and Glenmark regarding that infringement. GSK admits that this Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a). To the extent that Counterclaim Paragraph 48 contains any other or additional averments, GSK denies them.

**COUNTERCLAIM PARAGRAPH NO. 49:**

Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b).

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 49:**

GSK does not contest venue in this Court for this Action.

**COUNTERCLAIM PARAGRAPH NO. 50:**

This is an action based on an actual and justiciable controversy between Glenmark and GSK concerning the invalidity and/or infringement of U.S. Patent No. 6,166,046

(“the ’046 Patent”), U.S. Patent No. 6,291,488 (“the ’488 Patent”), and U.S. Patent No. 5,998,449 (“the ’449 Patent”) (collectively, “the asserted patents”).

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 50:**

GSK admits that Glenmark, by infringing the ’046 Patent, the ’488 Patent, and the ’449 Patent, has created an actual and justiciable controversy between itself and GSK regarding that infringement. GSK denies that an actual or justiciable controversy exists between Glenmark and GSK regarding the presumptive validity of any claims of the ’046 Patent, the ’488 Patent, or the ’449 Patent. To the extent that Counterclaim Paragraph 50 contains any other or additional averments, GSK denies them.

**COUNTERCLAIM PARAGRAPH NO. 51:**

On information and belief, the ’046 Patent, entitled “Combination of Atovaquone with Proguanil for the Treatment of Protozoal Infections,” issued on December 26, 2000.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 51:**

GSK admits that the ’046 Patent, titled “Combination Of Atovaquone With Proguanil For The Treatment Of Protozoal Infections,” bears on its face an issue date of December 26, 2000.

**COUNTERCLAIM PARAGRAPH NO. 52:**

On information and belief, the ’488 Patent, entitled “Preventing Protozoal Infections,” issued on September 18, 2001.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 52:**

GSK admits that the ’488 Patent, titled “Preventing Protozoal Infections,” bears on its face an issue date of September 18, 2001.

**COUNTERCLAIM PARAGRAPH NO. 53:**

On information and belief, the ’449 Patent, entitled “Combination of Atovaquone with Proguanil for the Treatment of Protozoal Infections,” issued on December 7, 1999.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 53:**

GSK admits that the '449 Patent, titled "Combination Of Atovaquone With Proguanil For The Treatment Of Protozoal Infections," bears on its face an issue date of December 7, 1999.

**COUNTERCLAIM PARAGRAPH NO. 54:**

On information and belief, GSK is the current owner by assignment of the asserted patents.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 54:**

GSK admits that since March 31, 2001, GSK has been, and continues to be, the sole owner of the '046 Patent, the '488 Patent, and the '449 Patent and the sole owner of the right to sue and recover for any infringement of those patents. To the extent that Counterclaim Paragraph 54 contains any other or additional averments, GSK denies them.

**COUNTERCLAIM PARAGRAPH NO. 55:**

Glenmark denies that it infringes any valid and enforceable claim of the asserted patents.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 55:**

Denied.

**COUNTERCLAIM PARAGRAPH NO. 56:**

Based on GSK's filing of the Complaint, and Glenmark's denial thereof, an actual controversy has arisen and now exists between the parties as to whether Glenmark has infringed any valid and enforceable claims of the asserted patents.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 56:**

GSK admits that Glenmark, by infringing the '046 Patent, the '488 Patent, and the '449 Patent, has created an actual and justiciable controversy between itself and GSK regarding that infringement. GSK denies that an actual or justiciable controversy exists between Glenmark and GSK regarding the presumptive validity of any claims of the '046 Patent, the '488 Patent, or

the '449 Patent. To the extent that Counterclaim Paragraph 56 contains any other or additional averments, GSK denies them.

**COUNTERCLAIM PARAGRAPH NO. 57:**

Unless GSK is enjoined, Glenmark believes GSK will continue to assert that Glenmark is infringing claims of the asserted patents and will continue to interfere with Glenmark's business with respect to the manufacture, use, offer for sale, and sale of tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride per tablet ("the Accused Product").

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 57:**

GSK admits that Glenmark has infringed the '046 Patent, '488 Patent, and '449 Patent. GSK further admits that it filed the present action alleging, *inter alia*, infringement of the '046 Patent, '488 Patent, and '449 Patent by Glenmark and seeking, *inter alia*, injunctive relief against Glenmark to prevent Glenmark from further infringing these patents. GSK denies that filing the present action in response to Glenmark's infringement of the '046 Patent, '488 Patent, and '449 Patent, and to prevent further infringement by Glenmark of those patents, constitutes interference with Glenmark's business. GSK admits that Glenmark purports to seek a judgment enjoining GSK from asserting infringement of the '046 Patent, '488 Patent, and '449 Patent against Glenmark. GSK, however, denies that there is any factual or legal basis for any such injunction. To the extent that Counterclaim Paragraph 57 contains any other or additional averments, GSK denies them.

**COUNTERCLAIM PARAGRAPH NO. 58:**

Glenmark will be irreparably harmed if GSK is not enjoined from asserting the '046 Patent, '488 Patent, and '449 Patent and from interfering with Glenmark's business.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 58:**

Denied.

**COUNTERCLAIM PARAGRAPH NO. 59:**

Glenmark incorporates paragraphs 47-57 of the Counterclaims as if fully set forth herein.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 59:**

GSK restates and incorporates by reference its responses to the allegations contained in Counterclaim Paragraphs 47-58 as though fully set forth herein.

**COUNTERCLAIM PARAGRAPH NO. 60:**

Glenmark has not infringed, and is not infringing, and has not induced or contributed to, and is not inducing or contributing to the infringement of any claim of the accused patents, either literally or under the doctrine of equivalents.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 60:**

Denied.

**COUNTERCLAIM PARAGRAPH NO. 61:**

Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Glenmark requests a declaration from the Court that Glenmark does not infringe the claims of the asserted patents.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 61:**

GSK admits that Glenmark purports to seek a declaratory judgment of non-infringement of the '046 Patent, '488 Patent, and '449 Patent under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* GSK, however, denies that there is any factual or legal basis for any such declaratory judgment. To the extent that Counterclaim Paragraph 61 contains any other or additional averments, GSK denies them.

**COUNTERCLAIM PARAGRAPH NO. 62:**

Glenmark incorporates paragraphs 47-60 of the Counterclaims as if fully set forth herein.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 62:**

GSK restates and incorporates by reference its responses to the allegations contained in Counterclaim Paragraphs 47-61 as though fully set forth herein.

**COUNTERCLAIM PARAGRAPH NO. 63:**

The claims of the asserted patents are invalid for failure to satisfy one or more of the conditions for patentability specified under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112 and/or 119.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 63:**

Denied.

**COUNTERCLAIM PARAGRAPH NO. 64:**

Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Glenmark requests a declaration from the Court that the claims of the asserted patents are invalid.

**RESPONSE TO COUNTERCLAIM PARAGRAPH NO. 64:**

GSK admits that Glenmark purports to seek a declaratory judgment of invalidity of the '046 Patent, '488 Patent, and '449 Patent under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* GSK, however, denies that there is any factual or legal basis for any such declaratory judgment. To the extent that Counterclaim Paragraph 64 contains any other or additional averments, GSK denies them.

**COUNTERCLAIM PRAYER FOR RELIEF:**

**WHEREFORE**, Glenmark respectfully prays that this Court enter judgment in its favor and grant the following relief:

A. Dismissing GSK's Complaint with prejudice and denying each and every prayer for relief contained therein;

B. Declaring that Glenmark has not infringed any claim of the '046 Patent, the '488 Patent, and the '449 Patent, and that Glenmark has a lawful right to manufacture, market, and sell tablets containing 250 milligrams of atovaquone / 100 milligrams of proguanil hydrochloride per tablet;

C. Declaring that the claims of the '046 Patent, the '488 Patent, and the '449 Patent are invalid;

D. Declaring that the claims of the '046 Patent, the '488 Patent, and the '449 Patent are void and unenforceable;

D. Enjoining GSK, its officers, employees, agents, representatives, attorneys and others acting on its behalf, from threatening or initiating infringement litigation against Glenmark or its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Glenmark, or charging them either orally or in writing with infringement of any patent asserted against Glenmark;

I. Awarding to Glenmark such further relief as this Court may deem necessary, just, and proper.

**ANSWER TO COUNTERCLAIM PRAYER FOR RELIEF:**

GSK denies that Glenmark is entitled to any relief from GSK or the Court, either as prayed for in its Counterclaims or otherwise.

GSK further denies each allegation contained in Glenmark's Counterclaims that was not specifically admitted, denied, or otherwise responded to in this Answer To Glenmark Generics Inc., USA's Counterclaims.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ James W. Parrett, Jr.*

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October 28, 2009  
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**CERTIFICATE OF SERVICE**

I, hereby certify that on October 28, 2009, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Steve L. Caponi, Esquire  
Alisa E. Moen, Esquire  
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I also certify that copies were caused to be served on October 28, 2009 upon the following in the manner indicated:

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*/s/ James W. Parrett, Jr.*

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